REMARKS

Claims 1-26 are pending. Claim 26 has been newly added. Claims 1, 15-17 and 26 are in independent form. Favorable reconsideration and allowance of the subject application are respectfully requested in view of the following comments.

Rejections Under 35 USC §103

Claims 1-6 and 17-21 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,432,441 (*Bealin-Kelly et al.*) in view of U.S. Patent No. 4,271,142 (*Puglia et al.*) and U.S. Patent No. 4,260,596 (*Mackles*). Claims 1-25 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,060,078 (*Lee*) in view of U.S. Patent No. 4,800,087 (*Mehta*), U.S. Patent No. 4,753,790 (*Silva*), U.S. Patent No. 4,260,596 (*Mackles*), and U.S. Patent No. 6,432,442 (*Buehler et al.*). Applicants respectfully traverse these rejections, in view of the comments set forth below.

Claim 1 is directed to a texture masking dosage form comprising (a) a unitary soft core, which is comprised of a plurality of active agent particles having an average size of greater than about 50μm, a hydrocolloid, and water, and (b) a brittle shell encasing the soft core in an amount of from about 20% to about 50% of the total weight of the texture masking oral dosage form and a thickness of from about 500 μm to about 3000 μm, wherein the weight ratio of active agent particles to shell is from about 1.0:0.5 to about 1.0:15 in the texture masking oral dosage form.

As noted previously in Applicants' response dated March 25, 2009, *Bealin-Kelly et al.* discloses a throat drop that has an edible shell (from 60% to 95%) and an aqueous filling (from 5% to 40%). The filling includes a throat relief agent, water, and a vesicle-forming agent,

which encapsulates the throat relief agents. *Bealin-Kelly et al.* states that the vesicles have a number average particle size of from about 1 to about 100 μm.

In contrast, Claim 1 of the present invention requires that the active agent particles have an average size of greater than about 50 μm. Applicants respectfully submit that the vesicles disclosed in *Bealin-Kelly et al.* are NOT the same as the active agent particles recited in Claim 1. In fact, *Bealin-Kelly et al.* states that the vesicles encapsulate the active ingredients. *See Bealin-Kelly et al.*, col. 1, lines 38-40. Thus, the active agent particles cannot be the same as the vesicles. And the fact that the vesicles have a number average particle size of from about 1 to about 100 μm does not mean that the active agent particles have the same particle size. As such, Claim 1 is patentable over *Bealin-Kelly et al.*

Puglia et al. is cited for disclosing an antacid tablet that has a center portion containing an antacid in the form of a liquid, cream or gel, where gelatin and pectin may be included as possible thickeners in the gel and cream center portion.

Mackles is cited for disclosing an edible unit dosage form having an outer shell and a liquid or gel center containing an active agent. The thickness of the shell may vary in the range of about 0.5 to about 3.0 mm.

However, neither *Puglia et al.* nor *Mackles* remedy the deficiencies of *Bealin-Kelly et al.*, since *Puglia et al.* and *Mackles* do not teach or suggest active agent particles having an average size greater than about 50 μm.

As such, claim 1 is patentable over *Bealin-Kelly et al.*, *Puglia et al.* and/or *Mackles*, whether considered separately or in any proposed combination.

Lee discloses a chewable pharmaceutical dosage form having a core containing an active ingredient and an outer layer. As noted by the Examiner, *Lee* does not teach (i) the use of ibuprofen in the disclosed dosage form, (ii) the particle sizes for the active agent, (iii) an outer shell that is about 20% to about 50% of the total weight of the dosage form, or (iv) that the outer shell has a thickness of about 500 to 3000 microns. *See* Office Action, p. 5, lines 6-10. Furthermore, the Examiner concedes that *Lee* does not teach an aqueous soft core, which includes water and a hydrocolloid. *See* Office Action, p. 8, lines 1 and 2.

Mehta discloses a chewable taste masked pharmaceutical dosage form. The Examiner states that "Mehta is cited solely for the teaching of the claimed active agents that can be delivered through chewable dosage form." *See* Office Action dated June 9, 2009, p. 10, lines 9 and 10.

Silva teaches a coated comestible having a substantially anhydrous core coated with a hard outer shell. Suitable cores include chewing gums, candies, nuts, licorice, and jellies. *See Silva*, col. 3, lines 20-25.

Mackles discussed previously, discloses an edible unit dosage form having an outer shell and a liquid or gel center containing an active agent, where the outer shell has a thickness that may vary in the range of about 0.5 to about 3.0 mm. However, *Mackles* does not disclose or suggest that the outer shell is brittle in any way.

Buehler et al. discloses a chewable product with a gelatin matrix that may include a hydrocolloid and water.

Applicants respectfully submit that the proposed combination of *Lee*, *Mehta*, *Silva, Mackles*, and *Buehler et al.* is based upon hindsight reconstruction. The Examiner has

selectively taken bits and pieces from each of these references to recreate Applicants' invention, after first seeing the blueprint provided by Applicants.

In attempting to reconstruct each feature of Applicants' invention, the Examiner has relied primarily on *Lee*, stating that *Lee* contains an enabling disclosure of a dosage form with a unitary core. The Examiner then relies on *Mehta* for teaching the claimed active agents. Next, *Silva* is brought into the mix for teaching a crunchy coating around a substantially anhydrous core. In addition, *Mackles* is relied upon for teaching the thickness of a shell surrounding a core. Lastly, *Buehler* is relied upon for disclosing a core that includes water and a hydrocolloid. Yet, in piecing together the mosaic, the Examiner has not provided a sufficient rational basis as to why one skilled in the art would be motivated to make each of the substitutions or modifications. It appears that the Examiner's focus is solely on recreating the invention, rather than looking at the problem Applicants were trying to solve. In particular, the Examiner has not explained why one skilled in the art would have modified the soft cores taught in *Lee*, *Mackles*, and/or *Silva*, which are understood to be anhydrous, with the core taught by Buehler which includes water and a hydrocolloid. "[T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." MPEP 2141.III, quoting KSR International Co. v. Teleflex Inc., 550 U.S. 398, 82 USPQ2d 1385, 1396 (2007). Without the benefit of hindsight after a reading of Applicants' invention, one skilled in the art would not have modified the core in such a manner. Accordingly, Applicants maintain that the § 103 obvious rejections of the pending claims are based on hindsight reconstruction, which is not permissible. Applicants respectfully request that the obviousness rejections be withdrawn.

Claims 15, 16 and 17 are directed to compositions that are similar to the composition of Claim 1 in many respects. Claims 15, 16 and 17 all include the features of Claim 1. Accordingly, for at least the same reasons discussed above for Claim 1, Claims 15, 16 and 17 are patentable over the proposed combination of *Bealin-Kelly et al.*, *Puglia et al.* and/or *Mackles,* or the proposed combination of *Lee*, *Mehta*, *Silva, Mackles*, and/or *Buehler et al.*

New Claim 26 is also directed to a composition that is similar to the composition of Claim 1, except that Claim 26 is a product by process claim. As such, Claim 26 includes processing limitations. As such, for at least the same reasons discussed above for Claim 1, Claim 26 is patentable over the proposed combination of *Bealin-Kelly et al.*, *Puglia et al.* and/or *Mackles,* or the proposed combination of *Lee*, *Mehta*, *Silva, Mackles*, and/or *Buehler et al.*

The remaining claims directly or indirectly depend from Claims 1, 15, 16 or 17. Therefore, each of the remaining claims is also patentable for the reasons stated above.

Accordingly, Applicants assert that the presently claimed invention would not have been obvious to a person of ordinary skill in the art at the time the claimed invention was made in light of these references. Thus, Applicants respectfully request that this rejection under 35 USC §103(a) be withdrawn.

Conclusion

For the foregoing reasons, the present application is in condition for allowance. Accordingly, favorable reconsideration of the amended claims in light of the above remarks and an early Notice of Allowance are courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned Attorney at the below-listed number.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/MCP0281USNP/VT.

Respectfully submitted,

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